

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY)	MDL NO. 1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	CIVIL ACTION: 01-CV-12257-PBS
)	
)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>)	Chief Magistrate Judge Marianne B. Bowler
<i>Inc. v. Abbott Laboratories, Inc.,</i>)	
No. 06-CV-11337-PBS)	

**MEMORANDUM OF LAW IN SUPPORT OF ABBOTT LABORATORIES, INC.’S
MOTION TO COMPEL DISCOVERY RESPONSES TO
ITS DOCUMENT REQUEST NOS. 37 AND 38**

Since serving its document requests on the Government over fourteen months ago, Abbott Laboratories, Inc. (“Abbott”) has repeatedly requested that the Government fully respond to requests seeking documents relating to: (1) proposed changes in laws or regulations that would have altered the methodology by which Medicare and Medicaid paid for drugs; and (2) other actions that the Government took or considered once it learned that Average Wholesale Price (“AWP”) exceeded actual acquisition costs for drugs. These requests seek the production, *inter alia*, of files from CMS’s Office of Legislation, as well as the Rulemaking Support File for the regulations adopting AWP as the basis for Medicare drug payments. Such documents are central to determining why Medicare and Medicaid continued to use AWP even though CMS knew the benchmark price exceeded providers’ acquisition costs for prescription drugs.

Incredibly, the Government is refusing to produce the documents requested. Despite seeking hundreds of millions of dollars in damages from Abbott, the Government has protested that responding to these requests will “consume considerable time and effort by both agency and DOJ staff” and refused to produce or even search for the documents. *See* June 27, 2007 Ltr.

from J. Draycott to D. Torborg (Ex. A). Efforts to persuade the Government to change its position have proven fruitless. Thus, with the close of discovery on the horizon and with the depositions of important witnesses from CMS underway, Abbott must now move to compel the Government to meet its discovery obligations.

The documents sought in this motion are unquestionably relevant to the Government's claims and Abbott's defenses. Among other things, material from CMS's Office of Legislation and its Rulemaking Support Files will shed light on the basis for CMS's repeated warnings in proposed regulations and to Congress that AWP exceeded true costs for prescription drugs, why CMS consistently advocated for lowering payment levels for prescription drugs in proposed regulations and to Congress, and why, at the end of the day, CMS and Congress chose to maintain a payment methodology based on AWP that exceeded actual prices paid for drugs. Discovery to date suggests that the answers to these questions will debunk the Government's claim that Abbott defrauded it into overpaying for prescription drugs.

I. BACKGROUND

On July 12, 2006, Abbott issued its first set of document requests to the Government, which included Document Request Nos. 37 and 38. Those Requests sought the following:

37. From January 1, 1965 to the end of the Relevant Claim Period, all Documents concerning the promulgation of any contemplated, proposed, or actual federal legislation, regulation, or policy concerning payment for drugs under Medicare or Medicaid, including any comments, suggestions, criticisms, surveys, studies, or data related to such legislation, regulation, or policy, including but not limited to those listed on the attached Schedule B.¹

38. All Documents relating to actions taken or considered by You to change the methodology to pay for drugs under Medicare Part B or Medicaid after becoming aware that AWP exceeded the average acquisition costs of Providers for drugs, including the Subject Drugs.

¹ Schedule B listed various proposed and final regulations pertaining to prescription drug payments, including 42 C.F.R. § 405.517, the 1991 regulation that permitted undiscounted AWP to be used for payment of Medicare Part B prescription drugs.

Abbott's First Set of Requests for Production to United States of America (Ex. B). As discovery progressed, it has become apparent that CMS's Office of Legislation and the agency's Rulemaking Support Files likely contain material responsive to these requests.

CMS's Rulemaking Support Files contain documentation tracking proposed regulations and the policy decisions that are made during the regulation process, including "drafts of the rules, internal comments received on the drafts, regulations logs, regulations specifications (if applicable), preliminary actuarial estimates, and internal recommendations." *See* CMS Record Retention Policy (Ex. C). A Rulemaking Support File is created for each proposed CMS regulation, including the April 25, 1991 proposed regulation that, when enacted in November 1991, established undiscounted AWP as the maximum allowed payment for drugs covered under Medicare Part B drugs. *See* 42 C.F.R. § 405.517 (1991). Despite CMS's policy of destroying such files 10 years after publication of the final rule, the Rulemaking Support Files for the 1991 regulation still exist. *See* June 6, 2007 Parker Dep. at 88-89 (Ex. D) (testifying that the Rulemaking Support Files still exist for previously proposed or final regulations and typically take one week to retrieve from the Federal Record Center). Aside from public comments to the proposed regulations, however, the Government has refused to produce documents from the Rulemaking Support File related to this key regulation. *See* June 27, 2007 Ltr. from J. Draycott to D. Torborg (Ex. A).

The Government similarly has refused to produce documents from CMS's Office of Legislation even though, by the nature of their roles, staff members from this Office frequently would have analyzed prescription drug pricing to communicate with Congress, prepare CMS officials for Congressional hearings, and propose legislation regarding drug payments.² *See*

² The Government has agreed to produce communications between the Office of Legislation and Congress related to prescription drug pricing, but it continues to withhold all other documents from this Office, including all

Overview, *available at* http://www.cms.hhs.gov/OfficeofLegislation/01_overview.asp (Ex. F) (describing the Office of Legislation's role in crafting legislative strategies, preparing for Congressional hearings, and shaping CMS's policy in connection with Congressional activity). Numerous witnesses have testified that CMS's legislative staff regularly communicated with Congress on the subject of prescription drug pricing. The Office of Legislation's files presumably would contain telling information regarding CMS's knowledge of drug prices, its understanding regarding AWP and spreads, and its efforts to change (or not to change) the methodology by which Medicare paid providers for Part B drugs. For example, evidence exists showing that in the mid-1990s, the Clinton Administration sought legislation that would base drug payments on providers' actual acquisition costs instead of AWP. The Office of Legislation's files would shed light on not only this proposal, which Abbott has been unable to locate, but also on CMS's repeated efforts to base their payment methodologies on actual acquisition costs. *See infra*, at pp. 8-10.

II. THE MATERIALS SOUGHT ARE RELEVANT

Documents from the Office of Legislation and the Rulemaking Support Files are relevant because they illuminate what the Government knew about prescription drug pricing and the spreads between AWP and actual acquisition costs, as well as the reasons for CMS's failure to change its payment methodology in spite of such knowledge. The Government's contrary suggestion that such evidence is not relevant disregards the important role that such evidence would play in discrediting the Government's allegations that it was duped or defrauded into paying more than it intended for prescription drugs. The Government further ignores this

(continued...)

internal documents analyzing drug pricing and payments that did not ultimately result in correspondence with Congress. *See* August 10, 2007 Ltr. from D. Torborg to J. Draycott (Ex. E).

Court's edict that "the great weight of authority holds that fairness to the defendant requires the government to make available all information relevant to the defense." *Ghana Supply Comm'n v. New Eng. Power Co.*, 83 F.R.D. 586, 593-94 (D. Mass. 1979) (collecting cases).

The core allegation of this lawsuit is that the federal and state governments were misled into paying "excessive reimbursement" for certain Abbott products (hereinafter, the "Subject Drugs") through the Medicare and Medicaid programs. Compl. ¶ 3. The Government contends that the prices reported in the pricing compendia for the Subject Drugs were "false, fraudulent, and inflated," and that the "Medicare and Medicaid programs relied upon [those prices] to set reimbursement rates for Abbott's customers." *Id.* ¶¶ 3, 59-60. Moreover, the Government claims that it "acted in justifiable reliance upon Abbott's misrepresentations" and that it would not have paid for the products at issue "[h]ad the true facts of Abbott's false price reporting as set forth in this Complaint been known to the United States." *Id.* ¶¶ 113-14.³

The Government must prove the elements of fraud to prevail in this case, including justifiable reliance, materiality, and causation. *See, e.g., Am. Heritage Bancorp v. United States*, 56 Fed. Cl. 596, 607 (2003) (finding that the government must prove the traditional elements of fraud claim by clear and convincing evidence); *United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 632 (S.D. Ohio 2000) (applying elements of fraud claim to the government), *aff'd*, 302 F.3d 637 (6th Cir. 2002). Evidence concerning whether the Government believed that AWP's equaled or approximated actual market prices is relevant to whether the Government justifiably relied upon those prices, and its policy decisions for continuing to pay for drugs based upon AWP despite such knowledge is relevant to causation. In short, if the Government used AWP despite (or because of) its true relationship to acquisition costs, then the

³ Along with its common law fraud claim, the Government has alleged that Abbott violated the False Claims Act, which itself is a fraud statute. *See United States ex rel. Karvelas v. Melrose Wakefield Hosp.*, 360 F.3d 220, 227 (1st Cir. 2004).

Government as plaintiff cannot claim to have been defrauded and cannot ascribe falsity to claims paid based on AWP.

This Court has repeatedly recognized that evidence of government knowledge regarding drug pricing and spreads is relevant to this case. *See* Oct. 26, 2006 Hr’g Tr. at 7 (Ex. G) (agreeing that the Government’s awareness that AWP did not reflect acquisition costs in the marketplace was a statute of limitations issue, a causation issue, and a *scienter* issue); *see also* Feb. 27, 2007 Hr’g Tr. at 38 (Ex. H) (acknowledging that Government knowledge may be “quite relevant” and at the “heartland” of this case). Indeed, the Court stated that evidence of “when the [Government] knowledge was acquired, and when it was reasonably acquired, and when it became . . . clear to the [G]overnment it was false . . . may win on a motion for summary judgment, at least for part of it.” *Id.* at 16. *See also*, Nov. 21, 2006 Trial Tr. at 6 (Ex. I) (“[I]t adds to the case about whether it’s unfair and deceptive. It depends what they heard, what they didn’t hear, what they knew, what they didn’t know. If they gave a blank check to them, ‘Go ahead and do it,’ that helps [the Defendants].”). Perhaps most importantly for purposes of the instant motion, this Court has recognized that a factual record on Government knowledge and the reasons behind the Government’s inaction in the wake of such knowledge was necessary in this case. *See* Feb. 27, 2007 Hr’g Tr. at 36 (Ex. H) (“[W]hat Centers for Medicare and Medicaid Services understood and knew and what they agreed to and what they didn’t . . . it’s relevant, not only to the statute of limitations, but it’s also relevant to – I think a very difficult area of the law is when the [G]overnment knows about a fraud . . . and it continues . . . I don’t know what the answer is under [the] False Claims Act, ***but at least we need a factual record.***”) (emphasis added).

In view of the above case law and comments from this Court, the Government cannot legitimately question the relevance of documents from the Office of Legislation and the Rulemaking Support Files showing the Government's knowledge about spreads and CMS's deliberate decision to use published AWP as the basis for drug payments despite knowing of such spreads.

A. Files from CMS's Office of Legislation

The Government's blanket refusal to search the files of the Office of Legislation is inconsistent with evidence suggesting that these files contain centrally relevant documents. A review of the evidence makes it abundantly clear that this Office has evidence to explain why CMS and Congress made the political decision to continue using AWP *even today* as the benchmark for drug pricing. *See* Scully Dep. at 364-66 (Ex. J) (testifying that the Government is still basing payments for drugs used in home infusion settings on 95% of AWP).

The mission of CMS's Office of Legislation makes it a key player in drafting legislation and preparing for Congressional testimony regarding prescription drug pricing. During the relevant time period, drug pricing and payment levels for providers consumed significant attention from Congress; the Office of Legislation necessarily focused extensively on these topics in the course of its duties. *See* Overview (Ex. F) (The Office of Legislation "works to ensure that the Agency speaks with a single, collective, clear voice to Congress in responding to multiple requests from Members and staff including Congressional testimony, reports to Congress, and responses to Office of the Inspector General and GAO reports."). Indeed, Robert Niemann, a drug payment policy analyst for CMS, has testified that individuals from the Office of Legislation attended meetings with members of Congress concerning drug payment policy issues, and that the concept of AWP was a frequent topic of conversation in these meetings. *See* Niemann Dep. at 71-72 (Ex. K). The Office prepared Mr. Niemann for these meetings and

always accompanied him. *Id.* at 69-70. To the extent that Mr. Niemann provided technical expertise to Congress in creating legislation on drug payment policies, those communications went through the Office of Legislation. *Id.*

CMS's Office of Legislation proposed legislation to Congress relevant to the issues in this case. For example, in a letter to Congressman Pete Stark, Michael Hash, CMS's Acting Administrator in 2000, summed up the Office of Legislation's repeated attempts to convince Congress to move away from AWP-based payments:

This Administration has repeatedly proposed legislation to Congress to change the manner in which outpatient drugs are paid. In 1997, HCFA proposed that payments in settings other than outpatient hospital departments would be based on actual acquisition costs, but Congress enacted legislation to pay 95 percent of the AWP instead. Knowing that such a policy would correct only a small fraction of the excessive payments, HCFA once again proposed actual acquisition costs in 1998. Congress let the 95 percent of the AWP stand. With so far to go, and believing that Congress would not abandon AWP, in 1999 and again in 2000, HCFA proposed that outpatient drugs be paid at a rate of 83 percent of AWP. Yet, Congress has not made any changes to the reimbursement rate of 95 percent of AWP to date.

Nov. 21, 2000 Ltr. from M. Hash to P. Stark, at 2 (Ex. L).⁴ Another CMS official, Kathleen Buto, similarly testified that the Office of Legislation was involved in developing the proposed legislation President Clinton referred to in his 1997 radio address, which characterized AWP as a sticker price and advocated paying providers based upon their actual costs for drugs. *See* Buto Dep. at 67-68 (Ex. M) & Dec. 13, 1997 Remarks by President Clinton (Ex. N); *see also* DeParle Dep. at 145-60, 239-40, 259-60 (Ex. O) (testifying that, as part of President Clinton's proposed 1998 and 1999 budgets, CMS suggested legislation that would have required Medicare to pay

⁴ CMS's Office of Legislation routinely coordinated responses to inquiries from Members of Congress, such as the response Mr. Hash sent to Rep. Stark. While the Government has agreed to produce the final correspondence sent to Congress on drug payment issues, it refuses to produce the internal documents that formed the basis for the content of CMS's letter to Congress (*i.e.*, documents demonstrating CMS's internal knowledge about AWP, spreads, and supposed overpayment). These documents are the subject of a pending motion to overrule the Government's assertion of the deliberative process privilege. *See* Abbott's Objections to Magistrate Bowler's August 13, 2007 Order [Dkt. # 4698].

providers for prescription drugs at actual acquisition costs).⁵ The Government's relevance objection ignores the testimony of witness after witness acknowledging that the Office of Legislation had extensive involvement in analyzing AWP and repeatedly attempted to convince Congress that the Government should cease basing its drug payment policies on AWP.

The documents produced from other sections of CMS likewise suggest that the Office of Legislation should have relevant evidence for this case. For instance, fax cover sheets indicate that CMS employees within the Office of Legislation were keeping the Office of Inspector General ("OIG") apprised of developments regarding changes in the way drug payments were calculated by Medicare and Medicaid. On March 2, 1998, personnel from the Office of Legislation sent a facsimile to OIG advising the office of language from President Clinton's 1998 budget bill that called for drug payments based upon actual acquisition costs and that would have required providers to include their actual acquisition costs for drugs in their request for payment. *See* Mar. 2, 1998 fax from M. Furletti to R. Vito (Ex. Q). Plus, the Office of Legislation is implicated indirectly in a February 20, 1997 e-mail urging carrier personnel to lobby Congress in favor of CMS's proposed legislation to base drug payments on providers' actual acquisition costs. *See* Feb. 20, 1997 E-mail from D. Sheridan (Ex. R). That e-mail quotes the FY1998 proposed budget as follows:

Proposal: Eliminate the mark-up for Medicare covered drugs and biologicals that are not currently paid on a cost or prospective payment basis (e.g., lupron or albuterol furnished by physicians, suppliers or independent dialysis facilities). Effective 1/1/98, payment would be made on the basis of the acquisition cost of the biller subject to a median limit.

⁵ When asked whether he communicated with Congress regarding payments for prescription drugs, Bruce Vladeck, CMS's administrator from 1993 to 1997, testified that "at the staff level there was continual conversation about th[e] issue," and then went on to volunteer that knowledge of a spread between AWP and market prices "was very widespread within the policy community in Washington, so that the Congressional staff and the HCFA staff and other HHS staff and, frankly, industry representatives, would have all seen the same documents, would all have shared the same sort of gossip and perceptions." Vladeck Dep. at 192-93 (Ex. P).

Rationale: There are numerous accounts of prices for drugs being charged to the Medicare program in excess of the market price; persons bill Medicare the “average wholesale price” (AWP) while receiving substantial discounts below the manufacturers’ published AWP. Studies by the HHS Inspector General have concluded that actual drug prices are well below the AWP rate. Elimination of the mark-up would mean that persons who bill Medicare for covered drugs would be paid for their professional services or items they furnish and not derive a profit from furnishing drugs incident to their service or item they furnish. In the case of pharmacies (who bill Medicare for self-administered drugs or biologicals under limited circumstances) a dispensing fee would be allowed in addition to their acquisition cost.

Id. Documents from the Office of Legislation considering this budget proposal are relevant to determining why CMS failed in their attempt to abandon AWP and whether the continued use of AWP was a deliberate decision based upon political expedience rather than fraud.

The Government itself recognizes the relevance of material relating to the legislative process. The Department of Justice recently subpoenaed the National Home Infusion Association (“NHIA”), an advocacy group for home infusion providers. *See* DOJ Subpoena (Ex. S). Among other things, the DOJ’s subpoena sought all communications NHIA had with legislators relating to the issues of drug reimbursement or pricing. Moreover, the Government has sought and received numerous documents from Abbott relating to its lobbying efforts, and the Government questioned Abbott’s Senior Director of Federal Government Affairs about Abbott’s efforts to influence legislation. The Government’s discovery against Abbott and NHIA, which was not limited to the Subject Drugs, simply cannot be reconciled with the Government’s claim that materials from CMS’s Office of Legislation are irrelevant to this case. Abbott should be entitled to discovery at least as extensive as that taken by the Government.

B. The Rulemaking Support File

The Rulemaking Support File maintained in connection with the central regulation at issue in this case, 42 C.F.R. § 405.517, likely contains material showing why CMS first decided to use AWP for drug payment purposes in 1991, what CMS understood regarding the spread

between AWP and market prices, and why CMS ultimately decided to abandon its proposal to pay 85% of AWP instead of paying 100% of AWP. A simple review of the publicly-available proposed and final regulation demonstrates that highly relevant, and potentially exculpatory, evidence resides in this Rulemaking Support File. In the 1991 proposed regulations for § 405.517, CMS sought payment levels at 85% of AWP because the agency “believe[d] that the Red Book and other wholesale price guides substantially overstate the true cost of drugs.” *See* Proposed Rule, 56 Fed. Reg. 25,792 (June 5, 1991) (Ex. T). CMS received a large number of public comments, including a number of letters from providers who asserted that the payment for drugs above acquisition cost subsidized CMS’s underpayment for other provider costs for which providers received no payment. *See, e.g.,* American Society of Clinical Oncology Comments (Ex. U) (urging CMS to refrain from lowering drug payment amounts because the current proposal did not take into account CMS’s failure to pay for wastage, breakage, inventory, sales tax, and other administrative costs). Thereafter, CMS adopted a final regulation setting drug payments at 100% of AWP. *See* 42 C.F.R. § 405.517 (1991).

This procedural history raises significant questions, as do CMS’s public comments, made both before and after this regulation was enacted, that AWP fails to approximate true market costs:

- What did CMS understand about the spread between AWP and actual acquisition costs at the time?
- Why did CMS propose basing payment on AWP, a figure that the agency understood exceeded market prices?
- Did CMS make a policy decision to set payment at 100% of AWP to make up for or cross-subsidize the inadequate (or non-existent) dispensing fees it was paying to providers?
- Why did CMS not use 85% of AWP as its payment methodology, as originally proposed, if it believed AWP overstated actual market prices?

- Why did CMS not reimburse providers at their actual acquisition cost if that truly was the goal of its reimbursement system?
- Was CMS actually fooled or defrauded into paying providers for drugs at AWP, or did it make a conscious decision to do so, and why?

Now that fifteen years have passed since this Regulation was proposed and implemented, witnesses' memories have faded and documents have been destroyed. The Rulemaking Support File may be the only means to answer questions that must be resolved before the Government can claim to be a victim of fraud. *See Gagne v. Reddy*, 104 F.R.D. 454, 456 (D. Mass. 1984) ("Relevancy [must be] broadly construed at the discovery stage of litigation and a request for discovery should be considered relevant if there is *any* possibility that the information sought may be relevant to the subject matter of the action.") (internal quotation marks omitted; emphasis in original).

Similarly, the Rulemaking Support Files for other regulations concerning drug payments likely contain material relevant to the Government's knowledge of spreads and thus should be produced. For instance, the Rulemaking Support File maintained in connection with the 1998 regulation that set payment at 95% of AWP as published in the Red Book should contain information on the Government's purposeful decision to discount AWP by only 5% despite overwhelming evidence and admissions from CMS, over the course of many years, that AWP exceeded the market prices for pharmaceuticals by much more than 5%. *See* 63 Fed. Reg. 58,814 (Nov. 2, 1998) (Ex. V) (implementing regulation setting payment at 95% AWP, and stating that "there are numerous reports by the OIG over the past 10 years showing significant discounts from the AWP are common and are not related to bulk purchases"). Indeed, the 1998 regulation was promulgated after a 1996 article that appeared in Barron's Magazine, which reported discounts of up to 85% for Abbott's drugs. *See* Bill Alpert, *Hooked on Drugs*, Barron's Magazine, June 10, 1996, at 15 (Ex. W). CMS's decision in 1998 to base payment on these

published AWP's is at the heart of the central question in this case: Was the Government fooled into paying amounts in excess of what it intended to pay?

III. THE DELIBERATIVE PROCESS PRIVILEGE DOES NOT APPLY WHOLESALE TO THE DOCUMENTS FROM THE OFFICE OF LEGISLATION OR THE RULEMAKING SUPPORT FILE

On top of its relevance objection, the Government has made a blanket objection to producing material from the Office of Legislation and the Rulemaking Support Files based upon the deliberative process privilege and has ignored Abbott's repeated requests for a privilege log identifying the documents it refuses to produce. This catch-all approach is improper under well-established case law. *See Pac. Gas & Elec. Co. v. United States*, 70 Fed. Cl. 128, 135 (2006) ("Blanket assertions of the [deliberative process] privilege are insufficient.") (internal quotation marks omitted); *Kaufman v. City of N.Y.*, No. 98-2648, 1999 WL 239698, at *4 (S.D.N.Y. 1999) ("This blanket approach to asserting the [deliberative process] privilege is unacceptable and is itself grounds for denying invocation of the privilege.").

The Government's position also contravenes the August 13, 2007 Order by Magistrate Judge Bowler. As it currently stands, the Order requires the Government to produce documents that it previously withheld under the deliberative process privilege that "expressly reference Abbott Laboratories, Inc. ('Abbott') and/or the subject drugs as well as those documents that concern the government's knowledge of the common use of spreads with respect to published AWP's." *See* Aug. 13, 2007 Order (Ex. X).⁶ If the Order stands, the Government will be required to search the Office of Legislation's files and the Rulemaking Support Files for

⁶ Abbott disagrees that the Government is permitted to withhold any documents pursuant to the deliberative process privilege and has filed objections to Magistrate Judge Bowler's Order with the District Court, which remain pending. *See* Abbott's Objections to Magistrate Bowler's August 13, 2007 Order [Dkt. # 4698]. Nonetheless, by ordering the production of documents addressing certain topics, Magistrate Judge Bowler has implicitly rejected the Government's position that it can make a blanket objection on the basis of the deliberative process privilege. The Government also has appealed Magistrate Judge Bowler's Order. *See* Gov't's Objections to Magistrate Bowler's August 13, 2007 Order [Dkt. #4697].

documents falling under the parameters of Magistrate Judge Bowler's Order. If the Government's production obligations expand as a result of the District Court's review of the Order, as Abbott believes they should for the reasons set forth in its objections to the Order, then the Government will be obligated to make an even greater production of documents from the Office of Legislation and the Rulemaking Support Files than contemplated in Magistrate Bowler's current Order.

Regardless of how this Court resolves the deliberative process privilege issue raised by Magistrate Judge Bowler's Order, the Government will be required to search the Office of Legislation and CMS's Rulemaking Support Files for responsive documents and either produce or log those documents. Considering the fast-approaching discovery deadline and the upcoming depositions of individuals who worked on legislation and regulations for CMS, further delay of that search makes no sense. The Government's refusal to search and log the material from the Office of Legislation and the Rulemaking Support Files violates its obligations irrespective of the scope of the deliberative process privilege. *See* Fed. R. Civ. P. 26(b)(5) ("When a party withholds information otherwise discoverable under these rules by claiming that it is privileged . . . , the party shall make the claim expressly and shall describe the nature of the documents, communications, or things not produced or disclosed in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the applicability of the privilege or protection.").

IV. BECAUSE THE BURDEN OF PRODUCING THE REQUESTED MATERIAL IS MINIMAL, FUNDAMENTAL FAIRNESS REQUIRES THE GOVERNMENT TO RESPOND TO ABBOTT'S REQUESTS

Finally, the Government's objection that production of documents from the Office of Legislation and the Rulemaking Support Files would be burdensome is not supported by the facts and furthermore should be rejected on basic principles of fairness. The Rulemaking Support

Files for the relevant regulations are easily accessible to current CMS staff. *See* Parker Dep. at 88-89 (Ex. D) (testifying that the Rulemaking Support File for the 1992 Regulations could be retrieved from the Federal Records Center within one week). Similarly, the Office of Legislation's files should be centrally located within that Office, and it should not be overly time-consuming for the Government to search those files for documents related to legislation or policies concerning prescription drug payment and the use of AWP for such purposes. In fact, the Government should have conducted such a search long ago when it was first subpoenaed for documents in 2003, or at least when it was asked to produce documents in this case over fourteen months ago.⁷

Even more fundamentally, the Government has accused Abbott of fraud, and seeks damages in the hundreds of millions of dollars. As a result, Abbott has been forced to incur substantial expense defending against these claims, including responding to the Government's broad discovery requests. Litigation, however, is a two-way street. What the Government is required to prove, Abbott is entitled to disprove. The Government's attempt to avoid the typical inconveniences or obligations that necessarily come along with the decision to sue for fraud should be rejected, as it can make no showing that "the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(2)(C).⁸ Moreover, due process

⁷ It appears that the Government has now made a limited search of the files of the Office of Legislation, locating approximately 2,600 documents pertaining to relevant proposed legislation, and the Rulemaking Support Files relating to six regulations implicating prescription drug payments, locating approximately 1600 documents. *See* Sept. 25, 2007 Ltr. from J. Draycott to D. Torborg (Ex. Y).

⁸ To the extent the Government claims that it would be burdensome to log the material for deliberative process privilege objections, its objection makes little sense and finds no support under the Federal Rules. *See* June 27, 2007 Ltr. from J. Draycott to D. Torborg (Ex. A) (citing the burden of reviewing and logging the material from the Rulemaking Support File). In order to assert the deliberative process privilege properly, a responsible agency official must review the material in order to determine if it falls within the privilege. *See United States v. Salemme*, Nos. 94-10287-MLW, 97-10009-MLW, 1997 WL 810057 (D. Mass. Dec. 29, 1997); *Grossman v. Schwarz*, 125 F.R.D. 376, 381 (S.D.N.Y. 1989). The burden of creating a log therefore arises every time the Government asserts the deliberative process privilege. The naked claim by Government attorneys that much of the material sought *might* be withheld based upon the deliberative process privilege, does not excuse the Government

requires that the Government, in seeking millions of dollars from private litigants, not unjustly impede discovery, but instead endeavor to obtain a just and fair result. *See, e.g., United States v. Moss-American, Inc.*, 78 F.R.D. 214, 217 (E.D. Wis. 1978) (“The government is held to a high standard of conduct in civil litigation, its dominant purpose being to assist the court in arriving at a just and true resolution.”); *Sperry & Hutchinson Co. v. FTC*, 256 F. Supp. 136, 142 (S.D.N.Y. 1966) (“In civil actions, also, the ultimate objective is not that the Government ‘shall win a case, but that justice shall be done.’”) (citation omitted). The Government’s burden objection loses sight of Abbott’s due process rights and the liberal discovery policy of the Federal Rules. Failure to produce the evidence requested by Abbott violates those due process rights.

CONCLUSION

For the reasons set forth above, the Court should grant Abbott’s Motion to Compel Discovery in Response to Abbott Laboratories, Inc.’s Document Request Nos. 37 and 38, and order the Government to produce documents from CMS’s Office of Legislation and its Rulemaking Support Files pertaining to legislation or regulations concerning the payment for drugs under Medicare or Medicaid, including documents referring to the spread between AWP and provider’s actual acquisition costs. In the event the Government withholds any such documents pursuant to the deliberative process privilege, the Court should order the Government to provide a privilege log pursuant to Federal Rule of Civil Procedure 26(b)(5) detailing each

(continued...)

from its obligation to search for all documents responsive to Abbott’s requests and to log the material that a responsible agency official deems privileged.

withheld document and evidence supporting the efforts undertaken by the Government to determine that the privilege applies to each document.⁹

Dated: October 11, 2007

Respectfully submitted,

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⁹ See Abbott's Memorandum in Support of Its Renewed Motion to Compel Evidence Withheld Under the Deliberative Process Privilege at 10-13 [Dkt. #3959] (setting forth the proper procedure that the Government must follow in asserting the deliberative process privilege over documents).